

Canadian Association of General Surgeons Evidence Based Reviews in Surgery. 9. Risk factors for retained foreign bodies after surgery

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CAGS Evidence Based Reviews in Surgery

In September 2000, the Canadian Association of General Surgeons (CAGS) initiated a program titled "CAGS Evidence Based Reviews in Surgery" (CAGS-EBRS) to help practising clinicians improve their critical appraisal skills. During the academic year, 8 clinical articles are chosen for review and discussion. Both methodologic and clinical reviews of the article are performed by experts in the relevant areas. The *Canadian Journal of Surgery* publishes 4 of these reviews each year. Each review includes an abstract of the selected article and summarizes the methodologic and clinical reviews. We hope that readers will find these useful and learn skills that can be used to evaluate other articles. For more information about CAGS-EBRS or about participating in the program, email mckenzie@mtsinai.on.ca

Selected article

Gawande AA, Studdert DM, Orav EJ, Brennan TA, Zinner MJ. Risk factors for retained instruments and sponges after surgery. *N Engl J Med* 2003;348:229-35.

Abstract

Question: What are the identifiable risk factors for retained foreign bodies in surgical patients? **Design:** Case-control study. **Setting:** A malpractice insurance agency and 10 hospitals in the state of Massachusetts from January 1, 1985 to January 1, 2001. **Participants:** Fifty-four patients with a total of 61 retained foreign bodies, and 235 control patients. **Assessment of risk factors:** Risk factors considered included a change in nursing personnel during surgery, excessive loss of blood, lack of complete count of sponges and instruments, fatigue of the surgical team from the lengthiness or lateness of the procedure and urgency of the surgery, obesity, unexpected intra-

operative developments, the involvement of multiple surgical teams, and the performance of more than 1 major procedure at a time. **Main outcome measure:** Retained sponge or instrument after a surgical procedure. **Results:** Multivariate analysis showed that 3 factors were significant: emergency surgery (risk ratio 8.8, 95%CI 2.4-31.9), unplanned change in the operation (RR 4.1, 95%CI 1.4-12.4) and body mass index (RR for each unit increment 1.1, 95%CI 1.0-1.2). **Conclusions:** The risk of retaining a foreign body after surgery is significantly increased in emergency surgery with unplanned changes in the procedure and in patients with a high body mass index.

Commentary

The principal author of this study, Atul Gawande, has been outspoken in bringing accounts of human mistakes in surgery to the public's attention, mainly through publications in the lay press. Few surgeons would argue that errors such as leaving for-

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foreign bodies behind following surgery are rare events. Similarly, surgeons and other health care workers would concur with the importance of the issue: leaving unintended foreign material in a patient at operation is a nightmare for surgeons, hospitals and patients. If one accepts the authors' estimate of incidence in the United States, surgeons inadvertently leave behind instruments and sponges at an alarming rate of 1500 cases per year.

The authors performed a case-control study to identify risk factors that lead to the retention of foreign bodies after surgery. A case-control study is the trial design most commonly used by epidemiologists to study causation or risk. Obviously, it would be unethical to perform a randomized controlled trial where subjects were randomly assigned to a group where an exposure has potential to harm. Because these particular adverse events are usually rare, a randomized controlled trial would be impracticable in any case.

Case-control studies are considered Level II evidence because the risk of bias, and thus the potential for an incorrect conclusion, is much higher than with randomized controlled trials or cohort studies. The characteristics of a case-control study are that (1) the subjects are not randomly allocated but instead the cases and controls are selected; (2) the outcome is present at the start of the study; and (3) other possible confounders are not controlled. In this study, the cases were accrued from a malpractice insurance agency in the state of Massachusetts and by reviewing incident reports from 10 hospitals. In total, 54 patients with 61 retained foreign bodies were included. The controls were matched to the cases by the type of procedure, by institution, and temporally within 6 months of the foreign-body retention. Ten patients who fit these criteria were identified, following which 5 were randomly chosen; 4 of these made up the control group.

The selection of controls, with its potential for bias, is an important part of carrying out case-control studies. In addition to possible preconceived biases on the part of the investigator, there is potential for under- or over-matching of controls so that an association is detected when in fact there is none; conversely, over-matching may result in an association going undetected. Generally, controls should be selected from the same population and matched to cases by the most important prognostic factors. The characteristics of the 2 groups in this study (listed in table 2 of the article) are unfortunately the actual risk factors to be considered in the analysis, rather than baseline characteristics. The reader therefore remains uninformed as to how the 2 groups may be similar or dissimilar in other respects. One suspects that further data were unavailable because of the sources of the cases and controls.

A second potential bias relates to how the outcome was measured. Again, because case-control studies are performed retrospectively, methods of measuring the outcome in the 2 groups may differ. In the present study, the medical records of the control groups were reviewed by 4 surgical residents, who presumably knew the study objectives and that they were reviewing the charts of control patients. Thus, there may be some bias in interpreting the data. Since the case data were obtained from malpractice records, it is difficult to know whether the outcome variables were measured in the same way.

Because of the nonexperimental design of case-control studies, one can conclude there is an association between a risk factor and the outcome but cannot conclude that the risk factor actually causes the outcome. However, if the temporal relationship seems appropriate, there is a dose response and the association is strong, it leads credence to the like-

lihood that the factor is significant. The authors looked at several variables and found 3 to be statistically significant: emergency surgery (risk ratio 8.8; 95% confidence interval 2.4–31.9), unplanned change in the operation (RR 4.1; CI 1.4–12.4) and body mass index (RR for each 1-unit increment 1.1; CI 1.0–1.2). While all 3 are significant, the 9-fold increase in the risk of retaining a foreign body during emergency surgery is striking. Because the sample size is small, the 95% confidence intervals are quite wide. The authors did not report whether multiple risk factors increased the likelihood of a retained foreign body.

There are limitations to this study: the small sample size, the control group and cases coming from 2 different sources, and the difficulty in assessing the comparability of the 2 groups. Nonetheless, this article is important for 2 reasons. First, it provides data in the relatively new field of medical error. It is likely that it will be referenced for years, since to date it is the most comprehensive publication on the subject of inadvertent retained foreign bodies in surgery. Second and of equal importance, by its very presence the paper brings attention to the subject of retained instruments and sponges, and alerts clinicians to some of the high-risk situations where errors are more likely to occur: in emergency operations, when there are unplanned changes in procedure and when the patient is obese.

One can assume that no surgeon whose misadventure became a data-point in this study planned for such an outcome to occur. Surgeons have not been taught to consider the potential for this kind of misadventure while operating on patients with the risk factors identified by this study. The paper of Gawande and colleagues should help to raise awareness and thereby change operating-room culture.

Published articles on medical errors have proliferated in the last 5

years. Common themes in the current literature are the presence of system defects and human factors that predispose to mistakes that may culminate in adverse outcomes for patients. This article shows how both systemic flaws and individual, temporary human shortcomings can combine to produce catastrophic results for both patients and providers. Taking legal actions as a starting point for case-finding may not provide an accurate picture of incidence, but does drive the point home: if a sponge or instrument is left in the patient, a lawsuit may ensue with a result unfavourable to the surgeon. Leaving a sponge or instrument in a patient generally is indefensible, and damages are shared between hospital and surgeon. A "correct sponge

count" does not exonerate the surgeon, who is expected not to leave anything behind.

More work needs to be done. The authors have identified some risk factors for retained instruments and sponges, but other factors that have been associated with mistakes in clinical and other types of work were not subject to analysis. These include changeovers of house staff in teaching hospitals, ineffective communication patterns, worker fatigue and procedure complexity. Although the authors tried to capture surrogate measures for fatigue and complexity (case lateness and duration, involvement of multiple procedures), limitations in the identification of risk factors for low-frequency outcomes from large patient databases are inev-

itable. Ultimately, some of these factors will resist easy identification; others undoubtedly will be the subject of further scientific enquiry.

The authors have proposed sensible recommendations based on their findings. Sponge and instrument counts should be mandatory for all surgical and obstetrical procedures, without exception. They argue that radiographic screening of all high-risk patients (not just patients with incorrect counts) would be a cost-effective way to prevent injury. Until there is better evidence or a fuller evaluation, these recommendations for change of practice should be considered by all operating-room committees and individual surgeons.

Competing interests: None declared.

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